

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
4 March 2004 (04.03.2004)

PCT

(10) International Publication Number
WO 2004/017938 A3

(51) International Patent Classification⁷:
31/4178, 9/14, 9/16, 9/22

A61K 9/52,

(74) Common Representative: RANBAXY LABORATO-
RIES LIMITED; c/o DESHMUKH, Jay R., 600 College
Road East, Suite 2100, Princeton, NJ 08540 (US).

(21) International Application Number:

PCT/IB2003/003517

(22) International Filing Date: 25 August 2003 (25.08.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

860/DEL/2002

23 August 2002 (23.08.2002) IN

(71) Applicant (for all designated States except US): RAN-
BAXY LABORATORIES LIMITED [IN/IN]; 19, Nehru
Place, 110 019 New Delhi, Delhi (IN).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SHARMA, Puneet
[IN/IN]; A-25, Sector - 15, 201301 Noida, Uttar Pradesh
(IN). KUMAR, Pananchukunnath, Manoj [IN/IN]; 25
Laxmi Vihar Apartments, Block H-3, Vikas Puri, 110018
New Delhi, Delhi (IN). NAGAPRASAD, Vishnubhotla
[IN/IN]; 102, Surya Niwas Apartments, Balaji Nagar,
500072 Kukatpally, Hyderabad (IN). ROY, Sunilendu,
Bhushan [IN/IN]; Bungalow No. 7, Row House, Lokpu-
ram, Thane West, 400 601 Mumbai, Maharashtra (IN).
MALIK, Rajiv [IN/AT]; Haus 13/4, Unterer Schreiber-
weg, 1190 Wien (AT).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC,
SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

(88) Date of publication of the international search report:

13 May 2004

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: NITROFURANTOIN CONTROLLED RELEASE DOSAGE FORM

(57) **Abstract:** The present invention generally relates to controlled release dosage forms which provide immediate release and sus-
tained release of nitrofurantoin, and processes for their preparation. The controlled release dosage form includes a sustained release
portion and an immediate release portion. The sustained release portion includes nitrofurantoin and one or more pH dependent hy-
drophilic polymers. The immediate release portion includes nitrofurantoin.

WO 2004/017938 A3